Celebrex Capsules - Patient Information Sheet

This is a summary of the most important information about Celebrex. For details, talk to your healthcare provider.

FDA ALERT- 12/17/04: Emerging information suggests that there may be an increase in heart attack and stroke in patients taking Celebrex. Please ask your healthcare provider if Celebrex is right for you. For detailed information about these risks refer to the *FDA Alert for Practitioners*

What Is Celebrex?

Celebrex is a COX-2 selective non-steroidal anti-inflammatory medicine (NSAID) used to reduce swelling and soreness. Celebrex is used to

- Relieve symptoms of osteoarthritis (the arthritis caused by age-related wear and tear on bones and joints)
- Relieve symptoms of rheumatoid arthritis in adults
- Manage acute pain in adults (like the short-term pain you can get after a dental or surgical operation)
- Treat painful menstrual cycles
- Reduce the number of colon and rectum growths (colorectal polyps) in patients with a disease called Familial Adenomatous Polyposis, an inherited disease in which the rectum and colon are covered with many polyps. Celebrex is used along with the usual care for FAP patients such as surgery and exams of the rectum and colon.

Who Should Not Take Celebrex?

Do not take Celebrex if you:

- Ever had an allergic reaction to sulfa medicines
- Ever had asthma, hives or allergic-type reactions after taking aspirin or other NSAID or COX-2 medicines. Aspirinsensitive patients should not take Celebrex because it could cause severe narrowing of the airway (bronchospasm) and even death.
- Have advanced kidney disease
- Are pregnant, especially your last 3 months.

What Should I Do Before Taking Celebrex?

Tell your healthcare provider if you:

- Are trying to get pregnant, are pregnant, or are breast-feeding
- Have or had angina (chest pain), heart attack, or blocked artery in your heart
- Have kidney problems
- Have liver problems
- Have heart failure
- Have high blood pressure
- Retain fluids (hold extra body water and swell)
- Had an allergic reaction to aspirin or other NSAID medicines
- Had a serious stomach problem in the past

• Have or had any other medical problems or allergies

Does Celebrex Interact with other Drugs or Food?

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Your healthcare provider may have to adjust your dose or watch you more closely if you take any of the following medications:

- Certain blood pressure medicines called ACE inhibitors
- Flurosemide (Lasix)
- Fluconazole or ketoconazole
- Lithium
- Phenytoin
- Warfarin (coumadin)
- Aspirin

Are There Other Risks?

Celebrex can cause stomach ulcers that bleed. The chance of this serious problem increases the longer you take Celebrex and with higher doses of Celebrex. Stomach bleeding can also happen suddenly while you take Celebrex. Stop taking Celebrex and call your healthcare provider right away if you get:

- A burning stomach pain
- Black bowel movements that look like tar
- Vomit that looks like blood or coffee grounds

Allergic reactions: Celebrex can cause serious allergic reactions, including swelling of the face, lips, tongue or throat, that may cause problems with breathing, swallowing, and wheezing. Serious skin reactions also have happened.

Liver damage: Stop taking Celebrex and tell your doctor right away if you have nausea, vomiting, tiredness, loss of appetite, itching, yellow coloring of skin or eyes, flu-like symptoms, and dark urine.

Kidney problems: Celebrex can cause serious kidney problems, including sudden kidney failure or worsening of kidney problems that you already have.

Fluid retention: Celebrex can cause fluid retention (holding of water in your body) and swelling. Fluid retention can be a serious problem if you have high blood pressure or heart failure.

Pregnancy: Do not take Celebrex during your last 3 months of pregnancy because it can harm your baby. Tell your doctor if you are pregnant or planning to become pregnant

Breast-feeding: Tell your doctor if you are breast-feeding.

How Do I Take Celebrex?

For osteoarthritis: 200 mg once a day or 100 mg twice per day For rheumatoid arthritis: 100 to 200 mg twice per day For pain: 400 mg to start, then 200 mg twice a day, if needed For colon polyps: 400 mg twice a day with food

Celebrex FDA Approval:1998

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